510(k) SUMMARY
K121763

NOV 2 7 2012

This summary of the 510(k) premarket notification for the MultiCross Support Catheter is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

GENERAL INFORMATION

Applicant:
Roxwood Medical, Inc.
150 Executive Park Boulevard, Suite 3700
San Francisco, CA 94134
U.S.A.
Phone: 408-373-4751
Fax: 415-467-1253

Contact Person:
Mehrdad Farhangnia
Chief Executive Officer
Roxwood Medical, Inc.
150 Executive Park Boulevard, Suite 3700
San Francisco, CA 94134
U.S.A.
Phone: 408-373-4751
Fax: 415-467-1253

Date Prepared: June 13, 2012

DEVICE INFORMATION

The MultiCross Support Catheter is a percutaneous catheter for use in the coronary and peripheral vasculature.

Trade Name:
MultiCross Support Catheter

Generic/Common Name:
Percutaneous Catheter

Classification:
21 CFR§870.1250, Class II

Product Code:
DQY

PREDICATE DEVICE(S)

- Vascular Solutions Twin-Pass™ OTW Dual Access Catheter (K072618)
- EndoCross ENABLER-P Catheter System (K092174)
- BridgePoint Medical Stingray Orienting Balloon Catheter (K080987)

INDICATIONS FOR USE

The MultiCross Support Catheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the coronary and peripheral vasculature and for guidewire exchange.

PRODUCT DESCRIPTION

The MultiCross Support Catheter is a sterile, single-use, triple lumen, over-the-wire, disposable percutaneous support catheter designed for use in conjunction with a steerable guidewire to access discrete regions of the coronary and peripheral vasculature for guidewire exchange.

The MultiCross Support Catheter consists of an inner shaft, outer sheath, and a proximal handle that allows for manual device manipulation and a means for flushing the catheter lumen. A key element of the device is a temporarily deployable and retractable distal Nitinol scaffold, which is visible through fluoroscopy when deployed by the user, and expands to the width of the artery to provide an anchoring to aid the user in establishing greater support near the treatment site.

Subsequent to conventional guidewire placement, therapeutic devices such as atherectomy devices, PTCA catheters, and/or stents may be used to provide therapeutic benefit. The MultiCross Support Catheter by itself does not provide therapeutic benefit beyond simple facilitation of guidewire support. The MultiCross Support Catheter is similar in its design and it achieves its intended use by means of the same mechanisms as the predicate devices.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the MultiCross Support Catheter are similar to the predicate devices. Performance data were provided to support the determination of substantial equivalence.

Feature	MultiCross Support Catheter (Subject Device)	Vascular Solutions Twin-Pass™ OTW Dual Access Catheter	EndoCross ENABLER-P Catheter System	BridgePoint Medical Stingray Orienting Balloon Catheter
510(k) Number	K_____	K052257	K092174	K080987
Indications for Use	The MultiCross Support Catheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the coronary and peripheral vasculature and for guidewire	The Twin-Pass Dual Access Catheter is to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional	The ENABLER-P Catheter System is intended to be used in conjunction with a steerable guidewire to access discrete regions of the peripheral vasculature and for	The BridgePoint Medical Stingray™ Orienting Balloon Catheters are indicated for directing, steering, controlling, and supporting a guidewire in order to access discrete regions

Feature	MultiCross Support Catheter (Subject Device)	Vascular Solutions Twin-Pass™ OTW Dual Access Catheter	EndoCross ENABLER-P Catheter System	BridgePoint Medical Stingray Orienting Balloon Catheter
	exchange.	devices, and for use during two guidewire procedures.	guidewire exchange.	of the coronary and peripheral vasculature.
Guide Catheter Compatibility	7F	5F	7F	6F
Working Length	135 cm	140 cm	107 cm	135cm
Guidewire Compatibility	0.014" Guidewire compatible; Up to three guidewires may be exchanged	0.014" Guidewire compatible; Up to two guidewires may be exchanged	0.035" Guidewire Compatible	0.014" Guidewire compatible;
Lumen	Triple	Dual	Dual	Triple
Distal Shaft Capability	The Nitinol scaffold provides distal anchoring and supports the advancement of the guidewire.	Standard Percutaneous Catheter Distal Shaft Structure (no support mechanism)	The balloon provides distal anchoring and supports the advancement of the guidewire.	The balloon provides distal anchoring and supports the advancement of the guidewire.

SUBSTANTIAL EQUIVALENCE

The MultiCross Support Catheter is substantially equivalent to Vascular Solutions Twin-Pass OTW Dual Access Catheter (K072618), the EndoCross ENABLER-P Catheter System (K092174, and the BridgePoint Medical Stingray Orienting Balloon Catheter (K080987). The subject device and the predicate devices are percutaneous catheters. The proposed indications for use for the MultiCross Support Catheter are substantially equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the MultiCross Support Catheter is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Performance Testing – Bench

Extensive bench testing was conducted on the MultiCross Support Catheter to evaluate the performance of the device and to support a determination of substantial equivalence to the predicate devices. Non-clinical testing assessed the following aspects of the device:

- Catheter Inspection (Visual Inspection/Physical Dimensions)
- Particulate Testing
- Radial Outward Force
- Contrast Flush Injection
- Simulated Use
- Torque Strength
- Flexibility and Kink Resistance
- Leak: - Liquid
  - Air

- Tensile Strength
- Corrosion Resistance Test
- Coating Integrity
- *In vivo* Animal Validation Study
- Biocompatibility
- Sterilization Validation
- Packaging and Shelf-life

All testing was performed in accordance with recognized standards.

Safety and Performance Testing – Animal

A GLP animal study was performed to evaluate the safety, performance and handling of the MultiCross Support Catheter in the coronary and peripheral vasculature as compared to a control device. Based on pathology and histopathology results, the safety acceptance criteria for the study were met.

Performance and handling observations were made based on detailed characteristics of the device. No untoward observations were found by the clinician.

Conclusion of Performance Testing

The collective results of the bench testing and the GLP animal study demonstrate that the MultiCross Support Catheter meets the established specifications necessary for consistent performance for its intended use and is substantially equivalent to the predicate devices.

CONCLUSION

The MultiCross Support Catheter is a percutaneous vascular support catheter and shares its design and mechanism of action with the identified predicate devices. The results of the bench testing and GLP animal study confirm that the MultiCross Support Catheter functions to its specifications, performs as intended and exhibits the appropriate characteristics of a percutaneous support catheter. The MultiCross Support Catheter is substantially equivalent to the predicate devices in terms of technological characteristics, intended use and performance. No new issues of safety or effectiveness are raised by the MultiCross Support Catheter.

SUMMARY

The MultiCross Support Catheter is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Roxwood Medical, Inc.
Mr. Mehdrad Farhangnia
Chief Executive Officer
150 Executive Park Blvd, Suite 3700
San Francisco, CA 94134

NOV 2 7 2012

Re: K121763
Trade/Device Name: MultiCross Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 16, 2012
Received: November 19, 2012

Dear Mr. Farhangnia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

Digitally signed by Matthew G. Hillebrenner
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13002132 72, cn=Matthew G. Hillebrenner
Date: 2012.11.27 14:56:12 -05'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K121763

Device Name: MultiCross Support Catheter

Indications For Use:

The MultiCross Support Catheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the coronary and peripheral vasculature and for guidewire exchange.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121763